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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,650	01/26/2004	Ramin Shahidi	Shahidi-001A	8812

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EXAMINER

ROZANSKI, MICHAEL T

ART UNIT	PAPER NUMBER
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3768

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/764,650

Applicant(s)

SHAHIDI, RAMIN

Examiner

Michael Rozanski

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/29/05, 2/13/06, 7/13/06
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Drawings

1. The informal (handwritten) drawings are not of sufficient quality to permit examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Applicant is given a TWO MONTH time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

Claim Objections

2. Claim 18 is objected to because of the following informalities:

-Claim 18 is written to depend upon claim 18. Claim 18 has been examined to depend upon claim 17, in order to expedite prosecution. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Art Unit: 3768

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 16, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "optionally" in claims 1, 2, 16, and 17 is vague since it is unclear whether the claimed invention must embrace a protocol admitting of referencing a view field, determination of coordinates, or a tracking system to orientation.

Claims 3-5, 16, and 17 recite the limitation "the display device." There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 11/045,013. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims all features of the current invention including a method for guiding a medical instrument to a target site within a patient comprising generating images, indicating a spatial feature of the target site, determining 3D coordinates of the target site in a reference coordinate system, tracking the position of the instrument, projecting a view field onto the display device, and projecting various indicia to the target site. Furthermore, the copending application claims a system for guiding a medical instrument to a target site in a patient, assisted by machine-readable code, as seen in claims 21-24.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 11-13 of copending Application No. 10/764,651. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims all features of the current invention including a method for guiding a medical

instrument to a target site within a patient, including capturing an ultrasonic image, identifying a spatial feature, determining coordinates of the target site, determining the position of the instrument, displaying from the perspective of the instrument, and displaying a set of indicia.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,167,296.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims all features of the current invention. Claim 1 of '296 is a method for facilitating a diagnostic or surgical procedure involving a subsurface target site in a patient. This includes acquiring 3D scan data, moving an instrument to a selected orientation, determining the instrument orientation, selecting a field of view, constructing the scan data, and displaying the perspective image. Claim 2 is a method wherein the view field is seen from the tip-end position of the instrument. Claim 3 is a method that includes simultaneously displaying the image from the instrument and the image from scan data construction.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3768

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Shahidi (US Patent No. 6,167,296).

Claims 1-19: Shahidi discloses a method for volumetric image navigation including fiducial markers 113, 114 attached to a patient's head to enable registration of images generated by previously obtained scan data, a surgical instrument 109 directed toward a target site, a display device 102, and a position tracking system having a sensing unit 105 that uses software to process signals to generate data indicating the location and orientation of the instrument (col. 5, lines 30-64). LEDs 110, 111 are mounted on instrument 109 that emit signals detected by sensors 106, 107, 108 mounted on the sensing unit 105 (col. 5, lines 45-53). The instrument 109 may be an endoscope or US transducer with tip 115 having a conical field of view indicated in the display 901 by the image 905 indicating the intersection of the field of view 116 with the surface of the skin (col. 6, lines 7-11; col. 10, lines 31-43).

Shahidi also discloses that the computer system 101, which includes a CPU 201 communicative with a memory 202, the video display 102, and optical sensors 106-108, is connected to the position tracking system (col. 6, lines 22-28). The computer

memory contains software means for operating and controlling the position tracking system (col. 6, lines 28-29). The memory stores protocols that are implemented by program modules, which cause the computer to receive and load scan data for the patient. The computer further reads data from the position tracking system to register the scanned data in 3D (col. 8, lines 18-31). The program then reads input data to enable user to select a field of view for display, wherein the image data is manipulated to generate the desired view, along with any selected reference markers, material opacities, colors, and the like (col. 8, line 32 – col. 9, lines 2).

7. Claims 1-19 are rejected under 35 U.S.C. 102(e) as being unpatentable by Steins et al (US Patent No. 6,733,458).

Claims 1-19: Steins et al. disclose a diagnostic medical ultrasound system and methods of using image based needle guidance. The ultrasound system 100 is configurable to acquire information corresponding to a plurality of 2D image planes of a patient for 3D reconstruction through a scan converter 112 (col. 5, lines 25-35). The system also includes location sensors 130, 134 that are capable of sensing location (i.e. position, orientation) and generating data representing the location, wherein the sensors may be attached to an ultrasonic probe 104 (col. 9, lines 24-32). Furthermore, a location calculator 126 is used to determine the absolute and/or relative position and/or orientation of the transducer 104 and the medical device 132 (col. 10, lines 1-14). In turn, the 3D graphics calculator 144 computes the projected and actual trajectories of the medical device and the intersection of the device with the portion of the subject

represented in the ultrasonic image (col. 10, lines 15-18). The output of the 3D graphics calculator 144 goes to the screen graphics calculator 142 which converts the trajectory data to graphical representations that can be superimposed on the image 118 (col. 10, lines 22-26). The output of the 3D graphics calculator also goes to the system controller 122, which supplies input to the needle target buffer 128, as does the location calculator 126 (col. 10, lines 61-63). The needle target buffer computes the location of the transducer 104, the imaging plane produced from the invasive device 132, and generates image data (col. 10, line 66 – col. 11, line 20).

Graphical representations, such as lines, dots, dashes, or colored regions, may also be used to indicate changes in elevation profile due to beam formation or transducer movement. These sets of cues indicate the deformation of the invasive device 132, as well as the predicted trajectory of the device in regards to the needle guidance system (col. 12, lines 21-45).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3768

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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